



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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January 28, 2015

Harbin Quanke Medi-Technical Development Co., Ltd.  
Xianglin Wang  
CEO  
No.42-1 Lane2 JingWei Str. Daoli Dist.  
Harbin, Heilongjiang, China 150010

Re: K141892

Trade/Device Name: QK-Therapeutic Apparatus; Models QK-C01A, QK-C01B,  
QK-C01CZ, QK-C01EZ, QK-S14, QK-C02FZ, QK-C02D

Regulation Number: 21 CFR 890.5500

Regulation Name: Infrared Lamp

Regulatory Class: Class II

Product Code: ILY

Dated: December 10, 2014

Received: December 29, 2014

Dear Xianglin Wang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Felipe Aguel -S

for Carlos Peña, Ph.D., M.S.  
Director  
Division of Neurological and  
Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K141892

Device Name

QK Therapeutic Apparatus; Models QK-C01A, QK-C01B, QK-C01CZ, QK-C01EZ, QK-S14, QK-C02FZ, and QK-C02D

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Indications for Use (Describe)

The subject device may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the device may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

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Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## Section 5 510(K) Summary

### 1. Prepared date: 2015-1-23

### 2. Submitter Information

Name	Harbin Quanke Medi-Technical Development Co.,Ltd.
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Tel	+86 451-84674063
Fax	+86 451-84671775
Contact person	Wang xianglin
E-mail	qkgs@vip.163.com

### 3. Device Information

Trade name	QK Therapeutic Apparatus
Model	QK-C01A, QK-C01B, QK-C01CZ, QK-C01EZ, QK-S14, QK-C02FZ, QK-C02D
Common name	Infrared therapeutic heating lamp
Classification name	lamp, infrared, therapeutic heating
Regulatory class	Class 2
Production regulation	21CFR Part 890.5500
Product code	ILY
Panel	Physical Medicine

### 4. Predicate Device

Submitter	C&H International Inc
Manufacturer	Chongqing Silicate Research Institute
Trade name	TDP Heat Lamps
Model	CQG-111A/B,CQG-222A/B/D,CQG-270A/B
Product code	ILY
510(K)	K020851

### 5. Device Description

QK Therapeutic Apparatus, including 7 different models, consists of Energy generator, Height adjustment knob, Support, and Control box. It is used to provide topical heating to the body by the energy generator. The energy generator is composed of many semiconductor ceramic piece, and it can emit multiple peak wide-band nanometer waves which can be absorbed by human.

The device C01A,C01B,C01CZ,C01EZ and QK-S14 are desktop style, while the other models are Floor Standing. The Emission spectrum ranges from 6K to 12K nm, the Energy Peak Value Wave Range is  $9300\text{nm} \pm 465\text{nm}$  and the All-direction



Eradiation Rate is at least 83 %,The energy generator shall be replaced after 15000 hours of usage.

## 6. Indications for Use

The subject device may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the device may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

## 7. Summary of Substantially Equivalent

The subject device and the predicate device have the same intended use, operation principle and Conformance standard, and have the similar technical data, see the Table 1

Table 1

Compared item	Subject Device Present application	Predicate Device K020851	Comment
Indications for use	The subject device may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the device may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	The TDP Heat Lamp may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the lamp may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	Same
Operation principle	The device's energy generator can emit infrared wave to provide topical heating for the purpose of temporary pain relief of muscular pain, arthritis, shoulder pain, back pain and joint stiffness.	The mineral curing plate of the TDP heat lamp can emit a infrared wave to provide topical heating for the purpose of temporary pain relief of muscular pain, arthritis, shoulder pain, back pain and joint stiffness	Same
Spectrum	6K~12Knm	2K~25Knm	Similar



Ranges			
Peak wave length	9300±465nm	10000±1000 nm	Similar
Length of generator	18.5~35.5cm	16.6-12.4cm	Similar
Lifetime of generator	15000h	1000~1500h	Similar
Control Timer	No or Yes	Yes	Similar
Power Supply	AC120V	220~240V	Similar
Power	160~230W	120~300W	Similar
Power Frequency	50~60Hz	50~60Hz	Same
Warm-Up Time	3 min	10min	Similar
Irradiation distance	20-30cm	30-40cm	Similar
Irradiation time	High:20-40min/turn Low:30-60min/turn	15-60min/turn	Similar
Maintain time	15-20min	15-20min	Similar
Skin Temperature	40-45°C	40-45°C	Same
Style	Desktop&Floor standing	Desktop&Floor standing	Same
Operating Environment	Temperature: 5°C~40°C Humidity: ≤85%RH	Temperature: 10°C ~ 40°C Humidity: 10%~ 95% RH	Similar
Storage Environment	Temperature: -40°C ~55°C Humidity : ≤85%RH	Temperature: 10°C ~40°C Humidity: 10% ~ 95% RH	Similar
Conformance standard	IEC60601-1(Safety), IEC60601-1-2(EMC)	IEC60601-1(Safety), IEC60601-1-2(EMC)	Same



From the comparison form above, the subject device and predicate device have the same Indications for use, Operation principle, Power Frequency, skin temperature , maintain time, Style and Conformance standard.

In the Spectrum Range, length of generator ,Generator lifetime, Warm-up time, Irradiation distance, Irradiation time items, the subject device is slightly different from the predicate device, but the subject meets the requirements of IEC60601-1, IEC60601-1-2 and performance, so these difference does not bring any problem of effectiveness and safety.

## 8. Performance Data

8.1 The subject device has tested and complied with the following voluntary recognized standards:

- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- IEC 60601-1-2 Medical Electrical Equipment-Part 1-2: General Requirements for Safety -Collateral Standard: Electromagnetic Compatibility-Requirements and Tests, 2007.

8.2 According to the performance test result in section 11of this submission ,the irradiation distance is 20-30cm, the irradiation time is 30-60min/turn, and the skin Temperature is 40-45°C.

## 9. Conclusion

The QK Therapeutic Apparatus is substantially equivalent to the predicate devices in K020851.